General

Guideline Title

Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015.

Bibliographic Source(s)

Ramar K, Dort LC, Katz SG, Lettieri CJ, Harrod CG, Thomas SM, Chervin RD. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. 2015 Jul 15;11(7):773-827. [53 references] PubMed

Guideline Status

This is the current release of this guideline.

This guideline updates a previous version: Kushida CA, Morgenthaler TI, Littner MR, Alessi CA, Bailey D, Coleman J Jr, Friedman L, Hirshkowitz M, Kapen S, Kramer M, Lee-Chiong T, Owens J, Pancer JP. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. Sleep. 2006 Feb 1;29(2):240-3. [8 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The quality of evidence (High-Very Low) and strengths of recommendations (Standard, Guideline, Option) are defined at the end of the "Major Recommendation" field.

Primary Snoring

The Task Force recommends that sleep physicians prescribe oral appliances (OAs), rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea [OSA]). (STANDARD)

OSA

- When OA therapy is prescribed by a sleep physician for an adult patient with OSA, the Task Force suggests that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)
- The Task Force recommends that sleep physicians consider prescription of OAs, rather than no treatment, for adult patients with OSA who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)
- The Task Force suggests that qualified dentists provide oversight—rather than no follow-up—of OA therapy in adult patients with OSA, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)

- The Task Force suggests that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances. (GUIDELINE)
- The Task Force suggests that sleep physicians and qualified dentists instruct adult patients treated with OAs for OSA to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

Definitions

Final Assessments of Levels of Bodies of Evidence

High: The Task Force is very confident that the true effect lies close to that of the estimate of the effect.

Moderate: The Task Force is moderately confident in the effect estimate. The true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.

Low: The Task Force confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of effect.

Very low: The Task Force has very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

American Academy of Sleep Medicine (AASM) Strengths of Recommendations

	Overall Quality of Evidence			
Assessment of Benefits versus Harms/Burdens	**High**	**Moderate**	**Low**	**Very Low**
Benefits clearly outweigh harms/burdens	STANDARD	STANDARD	GUIDELINE	OPTION
Benefits closely balanced with harms/burdens OR Uncertainty in the estimates of benefits versus harms/burdens	GUIDELINE	GUIDELINE	OPTION	OPTION
Harms/burdens clearly outweigh benefits	STANDARD	STANDARD	STANDARD	STANDARD

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Obstructive sleep apnea (OSA)
- Snoring

Guideline Category

Management

Treatment

Clinical Specialty

Dentistry

Internal Medicine

Sleep Medicine

Intended Users

Dentists

Physicians

Guideline Objective(s)

To replace the previous and update recommendations for the use of oral appliances (OAs) in the treatment of obstructive sleep apnea (OSA) and snoring

Target Population

Adult patients with obstructive sleep apnea (OSA) or primary snoring

Interventions and Practices Considered

1. Oral appliance (OA) therapy (custom, titratable appliance)
2. Follow-up
    - Survey for dental-related side effects or occlusal changes
    - Sleep testing
    - Periodic office visits

Major Outcomes Considered

- Systemic hypertension
- Snoring
- Sleep quality
- Oxygen desaturation index (ODI)
- Minimum oxygen saturation
- Arousal index
- % REM
- Sleep efficiency
- Daytime sleepiness
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

The Task Force members performed an extensive review of the scientific literature to retrieve articles which addressed at least one of the eleven patient, Population or Problem, Intervention, Comparison, and Outcomes (PICO) questions. The literature search was performed by the American Academy of Sleep Medicine (AASM) research staff using the PubMed and EMBASE databases. Though the search yielded all types of articles

with various study designs, for most PICO questions the analysis was limited to only randomized controlled trials (RCTs) as RCTs are considered a higher quality of evidence than observational, nonrandomized, or before-after interventional studies. The RCTs that were cited in the 2006 AASM review paper and 2006 practice parameter paper were included for data analysis if they met the study inclusion criteria. For PICO questions 7 and 11, due to lack of RCTs, they relied on prospective observational studies. The literature search in PubMed was conducted using a combination of medical subject headings (MeSH) terms and keywords. The MeSH terms were: Sleep Apnea Syndromes, Snoring, Orthodontic Appliances, and Mandibular Advancement/Instrumentation. The keywords were: sleep apnea, sleep apnoea, sleep-related breathing disorders, sleep-disordered breathing, oral, intraoral, dental, orthodontic, mandibular, tongue-retaining, tongue-stabilizing, occlusal, titratable, titrated, appliance(s), splint(s), device(s), oral appliances (OA), or snoring. The limits of the search (criteria that all had to be met) were: humans, English, all adults (no pediatrics), and RCTs. The RCT limitation was not used for PICO questions 7 and 11. The PubMed database was searched from January 1, 2004, through July 31, 2012, for any relevant literature published since the last guideline. This search was updated again on February 28, 2013, to capture the latest literature. A total of 324 citations were identified in PubMed and supplemented by pearling (i.e., checking the reference sections of search results for articles otherwise missed). The literature search in EMBASE was performed using a combination of disorder and treatment terms. The disorder terms were: sleep apnea, sleep apnoea, sleep apnea syndrome, sleep-related breathing disorders, or sleep-disordered breathing. The treatment terms were: orthodontic device, mandible reconstruction, oral, intraoral, dental, orthodontic(s), mandibular, tongue retaining, tongue-stabilizing, occlusal, titratable, or titrated. The presence of any one of these terms in the title or abstract of a publication would identify a potentially relevant article for inclusion in data analysis. The limits of the search were: humans, English, adults, and RCTs. The RCT limitation was not used for PICO questions 7 and 11. The EMBASE database was searched from January 1, 2004, through August 31, 2012. This search was updated again on February 28, 2013, to capture the latest literature and cross-checked with the results from the PubMed search to find any previously unidentified articles. A total of 53 citations were identified in EMBASE, yielding a total of 377 citations from both databases.

Abstracts from these articles were assessed by two Task Force members to determine whether they met inclusion criteria. However, if there were any questions on whether the abstract met the inclusion criteria, the article was reviewed in detail to determine whether to accept or reject. Articles were included for evaluation if they focused on treatment of snoring and/or obstructive sleep apnea (OSA) with OAs, and included only adult subjects. Included articles also had to address at least one of the eleven PICO questions identified ahead of the review process. Articles were accepted if they used either the apnea hypopnea index (AHI) or the respiratory disturbance index (RDI) as determined by an overnight polysomnogram (PSG) or the respiratory event index (REI) as determined by a home sleep apnea test. However, there were 3 articles that did not necessarily meet the above criteria, but were still included in the analysis. In two studies by Gauthier et al., RDI was defined as the combination of apneas, hypopneas and arousals per hour of sleep, while Gotsopoulos et al. defined AHI as the combination of apneas, hypopneas, and arousals per hour of sleep. The Task Force acknowledges that there are limitations to the direct comparisons made in this guideline due to the variety of ways AHI, RDI, and REI are defined and scored among the studies included. Articles were excluded if they focused on diagnosis, described the use of OAs to treat central or complex sleep apnea, or if they were studies on pediatric patients. A total of 51 articles met these criteria and were used for data extraction, meta-analysis, and grading.

Number of Source Documents

51 articles were used for data extraction, meta-analysis, and grading.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Final Assessments of Levels of Bodies of Evidence

High: The Task Force is very confident that the true effect lies close to that of the estimate of the effect.

Moderate: The Task Force is moderately confident in the effect estimate. The true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.

Low: The confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of effect.

Very low: The Task Force has very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of

effect.

Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review

Description of the Methods Used to Analyze the Evidence

Meta-analysis

Meta-analysis was performed with Review Manager 5.2 software to compare various types of oral appliances (OA) used to treat snoring and obstructive sleep apnea (OSA). OAs were categorized into the following types: custom, titratable; custom, non-titratable; non-custom, titratable; and non-custom, non-titratable. Meta-analysis was performed for each Patient, Population or Problem, Intervention, Comparison, and Outcomes (PICO) question by pooling data across studies for each outcome measure. All analyses were performed using the random effects model. The result of each meta-analysis is shown in a forest plot. Individual studies in the meta-analysis are identified in a table that includes the mean and standard deviation (SD) of the outcome measure and the number of patients. The pooled results are expressed as the total number of patients and mean difference between the experimental treatment and the control or between the baseline and final values of the outcome measure. The center of the black diamond at the bottom of the plot indicates the mean difference (i.e., average response or magnitude of effect) across all studies. The width of the black diamond represents the 95% confidence interval of the mean difference. The zero line represents no effect. If the black diamond does not touch the zero line, and lies beyond the clinical decision threshold, the treatment is considered either effective or ineffective depending on which side of the zero line the diamond lies.

It should be noted that for a number of PICO questions there was insufficient evidence to perform meta-analyses for certain comparisons and outcome measures. For example, the efficacy of OAs was only compared with continuous positive airway pressure (CPAP), as there was insufficient evidence to compare OAs to other therapies, such as conservative treatment or surgery. Therefore, the content of this guideline includes comparisons, outcome measures, and recommendations for which there was sufficient evidence. It should also be noted that meta-analysis of head-to-head studies was only performed when comparing the efficacy of OAs to CPAP. Due to insufficient head-to-head studies comparing different types of OAs (e.g., custom, titratable vs. custom, nontitratable), data on the efficacy of specific device types were pooled across studies and compared side by side. The meta-analyses are presented in the Appendix in the original guideline document.

Quality of Evidence

The assessment of evidence quality was performed according to a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) process (see the "Rating Scheme for the Strength of the Evidence" field). The GRADE system differs from other grading systems in that each study is not only evaluated for study design and risk of bias, but, additionally, an estimate of effect is generated for each outcome. The quality of evidence reflects the degree of confidence that the estimates of the effects are correct, and the quality of a body of evidence for each outcome is assessed as opposed to evaluating individual studies. Multiple aspects of quality are assessed including study limitations, imprecision, inconsistency of results, indirectness of evidence, and likeliness of publication bias.

A risk of bias analysis was performed on all randomized controlled trials (RCTs). Analyzing risk of bias includes reviewing aspects of conduct such as blinding, allocation concealment, loss to follow-up, or selective outcome reporting that could affect the quality of evidence. The GRADE process allows for the downgrading of the quality of evidence due to risk of bias. The grading of evidence also includes an analysis of imprecision, indirectness, and inconsistency. Imprecision refers to wide confidence intervals around the estimate of effect when there are relatively few patients and few events. Indirectness occurs when the question being addressed is different than the available evidence in terms of population, intervention, comparator, or outcome. There is inconsistency when there is unexplained heterogeneity of the results. A summary of the GRADE approach to rating quality of evidence is presented in Table 2 of the original guideline document.

All studies were assessed for study design and limitations to validity (bias) for each outcome of interest. Subsequently, the body of evidence for each outcome was assessed and graded, taking into account the results of the meta-analysis (if applicable) and other factors as described above. The final assessment was determined for each treatment and outcome measure. The results are reported as evidence profiles, for each PICO question, that include the number of studies, study design, limitations, inconsistency, indirectness, imprecision, and other considerations that went into determining the quality of evidence for each outcome of interest. Also reported are the number of patients that were studied, the overall effect that was calculated in the meta-analysis (reported as the *mean difference* [MD]), and a qualitative assessment of the relative importance of the outcome. Task Force members and American Academy of Sleep Medicine (AASM) staff extracted the data and graded the studies. The GRADE

summary of findings reports, along with the meta-analyses, are presented in the Appendix in the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Expert Task Force

To develop this guideline, the American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) commissioned a Task Force of seven members, three sleep medicine physicians and two dentists with expertise in the use of oral appliances (OAs), and two AASM research staff members experienced in guideline development. Prior to being appointed to the Task Force, the content experts were required to disclose all potential conflicts of interest (COI) according to the AASM's COI policy. None of the Task Force members had any conflicts that would preclude participation in this effort. The Task Force members performed an extensive review of the scientific literature to draft recommendations and supporting text for the use of OAs in the treatment of snoring and obstructive sleep apnea (OSA).

PICO Questions

PICO (Population, Intervention, Comparison, and Outcome) questions were developed based on both the questions raised in the 2006 AASM review paper and practice parameter and review of systematic reviews, meta-analyses, and guidelines published since then (see Table 1 in the original guideline document). The PICO format is an established framework for subsequently guiding literature searches targeted at addressing the PICO questions and developing evidence-based clinical practice recommendations. After a thorough review, editing, and approval of these questions by the Task Force members, the AASM Board of Directors approved the final list of PICO questions before the targeted literature search was performed.

Strength of Recommendations

The Task Force developed recommendations for the efficacy of OA treatment for snoring and OSA. Strengths of recommendation were assigned to these statements based on the strength of evidence and counterbalanced by an assessment of the relative benefits of the treatment versus the potential risks as delineated in Table 4 in the original guideline document. Particularly noteworthy on this table is that when the harm or burden clearly outweighs the benefit, a STANDARD strength of recommendation *against* the proposed therapy is given regardless of the overall quality of evidence.

Sections titled "Values and Trade-offs" appear in the original guideline document under each individual recommendation to explain the rationale leading to each recommendation. These sections are an integral part of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system and offer transparency to the process.

Rating Scheme for the Strength of the Recommendations

American Academy of Sleep Medicine (AASM) Strengths of Recommendations

	Overall Quality of Evidence			
Assessment of Benefits versus Harms/Burdens	**High**	**Moderate**	**Low**	**Very Low**
Benefits clearly outweigh harms/burdens	STANDARD	STANDARD	GUIDELINE	OPTION
Benefits closely balanced with harms/burdens OR Uncertainty in the estimates of benefits versus harms/burdens	GUIDELINE	GUIDELINE	OPTION	OPTION
Harms/burdens clearly outweigh benefits	STANDARD	STANDARD	STANDARD	STANDARD

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Approval of Recommendations

A draft of the guideline was available for public comment for a two-week period on the American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) Web sites. The Task Force took into consideration all the comments received and made decisions about whether to revise the draft based on the comments. The revised guideline was submitted to the AASM and AADSM Board of Directors who subsequently approved these recommendations.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Oral appliances (OAs) offer effective therapy for many patients with obstructive sleep apnea (OSA). These devices offer advantages over positive airway pressure (PAP) in that they do not require a source of electricity and are less cumbersome, especially with travel. OAs are well tolerated in most patients, and therapeutic adherence may be better than continuous positive airway pressure (CPAP).
- OAs reduce the frequency and intensity of snoring, improve sleep quality for both patients who snore and their bed partners, and improve quality of life measures.

Potential Harms

- Specific side effects of oral appliances (OAs) differ widely in types and severity, but most are of a dental nature: sore teeth, gum problems, sore jaw muscles, excessive salivation, difficulty chewing in the morning, dry mouth, and change in occlusion.
- The patient's history and exam, appliance preference, and review of any side effects should be taken into account to avoid device breakage, allergic reactions, or discomfort that leads to frustration or discontinuation of the therapy.

Contraindications

Contraindications

Temporomandibular disorder (TMD) has been the most common contraindication for oral appliances (OA) as a treatment for obstructive sleep apnea (OSA).

Qualifying Statements

Qualifying Statements

- The American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) expect these guidelines to have a positive impact on professional behavior, patient outcomes, and, possibly, health care costs. This guideline reflects the state of knowledge at the time of publication and will require updates if new evidence warrants significant changes to the current recommendations.
- The recommendations in this guideline define principles of practice that should meet the needs of most patients in most situations. This guideline should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably expected to obtain the same results. The ultimate judgment regarding propriety of any specific care must be made by the clinician (sleep physician and dentist), in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Ramar K, Dort LC, Katz SG, Lettieri CJ, Harrod CG, Thomas SM, Chervin RD. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. 2015 Jul 15;11(7):773-827. [53 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Jul 15

Guideline Developer(s)

American Academy of Dental Sleep Medicine - Professional Association

American Academy of Sleep Medicine - Professional Association

Source(s) of Funding

This was not an industry supported study.

Guideline Committee

Expert Task Force

Composition of Group That Authored the Guideline

Task Force Members: Kannan Ramar, MBBS, MD, Mayo Clinic, Rochester, MN; Leslie C. Dort, DDS, University of Calgary, Calgary, Alberta, Canada; Sheri G. Katz, DDS, Atlanta, GA; Christopher J. Lettieri, MD, Walter Reed National Military Medical Center, Bethesda, MD; Christopher G. Harrod, MS, American Academy of Sleep Medicine, Darien, IL; Sherene M. Thomas, PhD, American Academy of Sleep Medicine, Darien, IL; Ronald D. Chervin, MD, University of Michigan, Ann Arbor, MI

Financial Disclosures/Conflicts of Interest

Prior to being appointed to the Task Force, the content experts were required to disclose all potential conflicts of interest (COI) according to the American Academy of Sleep Medicine's (AASM) COI policy. None of the Task Force members had any conflicts that would preclude participation in this effort.

Disclosure Statement

Dr. Dort receives royalties from a tongue retaining device (MPowRx) and has financial interest in Zephyr. Dr. Lettieri is on the speakers' bureau of Teva Pharmaceuticals. Dr. Chervin is a board member of the American Academy of Sleep Medicine (AASM), consults for Zansors, and receives royalties from UpToDate and Cambridge University Press. The other authors have indicated no financial conflicts of interest.

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This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Academy of Sleep Medicine (AASM) Web site .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on April 25, 1999. The information was verified by the guideline developer on May 24, 1999. This summary was updated by ECRI on March 29, 2006. The updated information was verified by the guideline developer on April 21, 2006. This summary was updated again by ECRI Institute on January 26, 2016. The updated information was verified by the guideline developer on February 24, 2016.

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